



National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

December 29, 2000

Barrett N. Fountos  
U.S. Department of Energy  
Office of International Health Programs, EH-63/270CC  
19901 Germantown Road  
Germantown, MD 20874-1290

Dear Mr. Fountos:

Enclosed please find the Scientific and Management Progress Report for the time period 1 August 2000 to 31 October 2000 for the Chernobyl Research Program. I am also enclosing the most recent quarterly reports from the project Directors in Ukraine and Belarus, as well as the most recent quarterly report from Columbia University. I apologize for the lateness of this report; however, I was on travel for the studies during the months of October and early December, and as you know, November was occupied by the Tri-National meeting. Please feel free to contact me if you have any questions regarding this report.

Sincerely,

A handwritten signature in black ink, reading "Terry L. Thomas".

Terry L. Thomas, Ph.D.  
Senior Staff Scientist  
Chernobyl Research Unit  
Radiation Epidemiology Branch, NCI  
EPS, Room 7100  
6120 Executive Boulevard  
Rockville, MD 20852-7238  
Phone: 301-594-7658



Chornobyl Research Program  
SCIENTIFIC AND MANAGEMENT PROGRESS REPORT  
1 August 2000 to 31 October 2000

Submitted by: Terry L. Thomas, Ph.D. *TLT*

Date: 29 December 2000

I. Progress on "Epidemiologic Studies of Radiation Induced Thyroid Disease in Belarus (BelAm Thyroid Project) and Ukraine (UkrAm Thyroid Project)

A. BelAm Thyroid Project

The study began in 1997 with the selection of individuals to be included in the study cohort from the file of thyroid dose measurements at the Institute of Biophysics in Moscow (Selection 1). Selection 1 did not result in a sufficient number of responses to achieve the target cohort size of 12,000 subjects. Thus, in December 1999, the remainder of individuals in the dose file were selected and were traced for current address (Selection 2). As of 30 September 2000 current addresses were found for approximately 22,000 out of 38,725 potential study subjects. Initial invitation letters were sent to 3,672 subjects and 2,409 second/subsequent invitations were sent for baseline examinations during the period 01 July to 30 September; 332 subjects were invited to be screened for a second time. During this period 823 subjects were screened for the first time, bringing the total cohort size to 9,404. More than half of the subjects screened during the quarter were seen at the fixed center in Minsk, while 30 percent were seen at the fixed center in Gomel, and 17 percent were examined by mobile teams. The Project Director has been encouraged to develop a brochure describing the project and to add incentives, such as reimbursement for travel. As of 30 September 2000, newly diagnosed thyroid cancer was found in 35 of the screened subjects; and there were 9 benign thyroid neoplasms. Data entry is from 86% to 99% complete for most of the data collection forms for subjects who have been screened; however, there is a backlog in blood processing forms and final summary forms due to delays in the delivery of reagents to the laboratory. The reagent problem has been resolved, and it is anticipated that most of the backlog will be reduced during the next quarter.

In order to be able to provide funds to reimburse study participants for their travel expenses in reaching the screening sites, a contact was made with Belarusian Red Cross to serve as a conduit for this banking transaction. The Red Cross will manage these funds and provide quarterly allocation to the project agent for purchase of food items and other necessities (equivalent to US \$5 for each subject). A two year contract has been awarded, and initial funds have been transferred.

B. UkrAm Thyroid Project

The study in Ukraine began also in 1997 with the selection of 20,071 subjects (Selection 1) to be included in the study cohort selected from the list of people with thyroid dose measurements. Because Selection 1 did not generate sufficient response to achieve the target study population size, a second selection of 14,000 subjects (Selection 2) was taken in April 2000. As of 31 August 2000, addresses were found in the study oblasts for 16,904 of 32,572 potential study subjects. The brochure describing the study and reimbursement for travel expenses (equivalent to US \$5) are being provided to subjects. As of 01 October 2000, a total of 10,953 subjects (3,096 of them from Selection 2) had been examined. About 25 percent of the subjects were examined in the fixed center in Kiev, while 75 percent were examined by mobile teams. As of 31 August 2000, 18 newly diagnosed thyroid carcinomas were identified in the study cohort; there were 6 benign thyroid neoplasms. Considerable progress in key entering the backlog of study forms has been made, and it is anticipated that the backlog will be cleared by early 2001.

C. Other Progress

Both projects have now adopted the new quarterly report format with standardized tables describing study progress in detail. The most recent progress reports were submitted in the new format.

A joint clinical meeting was held in Minsk during September 2000 and was attended by clinicians from Belarus, Ukraine, and the U.S. The primary focus of the meeting was reaching consensus on criteria for fine needle aspiration and for particular thyroid diagnoses. Changes to the clinical sections of the operations manuals proposed by the American team were reviewed and revised. Final approval of the revisions was scheduled for the November Tri-National meeting.

A joint dosimetry meeting was held in September 2000. Its main purposes were to finalize the joint thyroid dosimetry questionnaires, to discuss analyses of the consistency of answers provided during previous dosimetry interviews, and to make plans for the preparation of a common methodology to estimate individual thyroid doses. The consensus of the group was that interviews of mothers of children who were under age 10 at the time of the Chornobyl accident would be the best respondents for these subjects.

The American epidemiologic team made a visit to Kiev and Minsk in October to work on plans for the training session for the second screening cycle and the revisions of the epidemiologic portions of the operations manual. A thorough review of the Belarusian data base was conducted, and the conclusion was that the data base is in excellent shape. A codebook had been developed for the data base. It was suggested that this be incorporated into a set of documentation which contains a list of quality control and edit checks performed routinely on the data base. A number of batch edits were suggested.

A Tri-National plenary session to assess study progress was scheduled for November 2000 in the United States. Belarusian, Ukrainian, and U.S. scientists were asked to participate in a series of discussions and workshops to be held in Rockville, Maryland.

II. Progress on "Study of Leukemia, Lymphoma, and Related Disorders in Ukrainian Clean-up Workers Following the Chornobyl Accident"

The protocol was approved by NCI's Chornobyl Oversight Panel and by NCI's Institutional Review Board.

The Ukrainian team vigorously pursued and completed most of the tasks agreed upon for the interim period between the end of phase 1 and the beginning of phase 2 (October 1, 2000). Investigators visited the proposed study Oblasts to discuss the phase 2 plan with the local public health services, regional oncology dispensaries, the local departments of the Chornobyl State Registry; to determine the potential sources of information for constructing the Leukemia Registry; and to select the local staff persons who will work on the study and acquaint them with the objectives of the study. In all of the Oblasts, the consent of local health officials was easily obtained, the sources of information on leukemia cases were identified, and the local staff persons were selected. Members of the American team visited Kiev in September 2000 to conduct a training session for local staff involved in data abstraction and quality control for the construction of the leukemia registry. A second visit was made in October to evaluate the progress of the abstracting and to assist in the development of the registry data base. At this time, a visit was made to Chernihiv Oblast to review the data sources for ascertaining all possible cases of leukemia diagnosed there. Detailed descriptions of the data sources in each oblast are being prepared and will be incorporated into the study documentation.

Considerable progress has been made in the exploration of methods for re-construction doses for study subjects. An international team, which includes the American and Ukrainian investigators from this study is working on the validation of a newly proposed method of dose re-construction. Early results show that the method shows some promise.

III. The quarterly progress report for each project is enclosed.